In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 19-1977V UNPUBLISHED

TERRY KLAUSEN,

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: June 2, 2021

Special Processing Unit (SPU); Findings of Fact; Onset; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

David John Carney, Green & Schafle LLC, Philadelphia, PA, for Petitioner.

Lynn Christina Schlie, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW¹

On December 30, 2019, Terry Klausen filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that he suffered a right shoulder injury related to vaccine administration ("SIRVA") caused by an influenza ("flu") vaccine administered to him on January 7, 2019. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters. The parties have now sought a determination of facts bearing on the adequacy of Petitioner's showing on certain elements of his claim.

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find that there is a preponderance of evidence that the onset of Petitioner's injury, specifically shoulder pain, occurred within 48 hours of his vaccine.

I. Relevant Procedural History

On August 17, 2020, Respondent filed a status report containing his counsel's preliminary assessment of the case. In that status report, Respondent noted certain records may be missing, and that certain issues may require additional factual development, including the site of vaccination and the onset of Petitioner's injury. (ECF No. 20).³

During a status conference held on September 2, 2020, I noted that the question of whether the onset of Petitioner's shoulder injury fits within the Table SIRVA timetable remained open. Respondent also indicated that there were gaps in the medical records for the months following Petitioner's vaccination and requested that Petitioner file his insurance benefits statement spreadsheet to ensure that all relevant medical records had been offered in the matter. I ordered the parties to file briefs for a factual ruling to determine onset, adding that after that issue is resolved, the question of additional unfiled records could be resolved.

Petitioner filed his Motion for Ruling on the Record, along with a letter from the vaccine administrator (Exhibit ("Ex.") 10) and Medicare Statement Notices (Ex. 11), on October 2, 2020. Motion for Finding of Fact ("Pet. Mot"), (ECF No. 24). Respondent filed his response on November 2, 2020. Respondent's Response to Petitioner's Motion for Finding of Fact ("Res. Resp.").⁴

II. Petitioner's Medical Records

Petitioner received a flu vaccine on January 7, 2019. Ex. 6 at 7. The vaccination record states the vaccine was administered in Petitioner's "deltoid" but does not specify the right or left arm. However, a letter from Petitioner's primary care physician, Dr. Kewal Aggarwal, stated that it was common practice in his office to give the flu shot in the right deltoid. Ex. 10.

³ Respondent also requested records for three years prior to vaccination and insurance benefit statements confirming there are no other pre-vaccination records. *Id.* Petitioner was ordered to file those records in an August 25, 2020 Scheduling order. (ECF No. 21). That same day, Petitioner's counsel contacted the Court objecting to filing these records, arguing that the Vaccine Rules do not require these records and they are not relevant in this case.

⁴ Respondent's counsel noted that medical personnel at DICP has not yet reviewed this case or provided a medical analysis. *Id.* at 11.

Four months later, on April 8, 2019, Petitioner first complained of right shoulder pain to Dr. Aggarwal. Ex. 6 at 6.⁵ At that time, Petitioner reported right shoulder pain "when playing 'Bowling' in 'Wii.'" *Id.* There is no mention of when the pain specifically began, or its trigger, however. Petitioner again saw Dr. Aggarwal on July 8, 2019. There is no mention of shoulder pain at that time. Ex. 6 at 3-4. Indeed, Petitioner had a physical examination at this time, which noted that Petitioner "does not appear to be in any acute distress." *Id.* at 3.

On August 13, 2019, Petitioner presented to Dr. Zubair Sarmast at Insight Orthopedics with complaints of right arm pain. Ex. 2 at 12. The record indicates that Petitioner's pain began in January of 2019 after a flu shot. *Id.* Petitioner's pain was worsening at that time with decreased range of motion, and he was assessed with "unspecified rotator cuff tear or rupture of right shoulder, not specified as traumatic." *Id.* at 13. An X-ray showed degenerative changes of the right shoulder, "which could indicate chronic rotator cuff disease." *Id.* at 14.

Petitioner again saw Dr. Sarmast for a follow-up after an ultrasound exam on September 3, 2019.⁶ According to Dr. Sarmast, the ultrasound "did show a high-grade partial tear of his supraspinatus tendon. He has a pacemaker and is unable to tolerate MRI. He had pain in his shoulder develop after a flu shot in 2019." Ex. 2 at 7. At that time, Petitioner reported some improvement in his pain, and received a steroid injection in his right shoulder. *Id.*

On October 10, 2019, Petitioner began physical therapy for shoulder pain, neck pain, and upper arm pain. Ex. 3 at 3. His intake form indicates that his injury occurred "Jan 2019" and the activity prior to his condition was "received flu shot". Ex. 2 at 12. The assessment at that time was "right shoulder pain consistent with rotator cuff pathology leading to subacromial impingement...." *Id.* at 18. At a follow-up examination with Dr. Sarmast, a second steroid injection was administered to Petitioner on October 29, 2019. Ex. 2 at 4, 6. Thereafter, between October 10, 2019 and January 16, 2020, Petitioner attended 16 physical therapy sessions. Ex. 5 at 3.

Petitioner next saw Dr. Sarmast on December 10, 2019 for a follow-up regarding his right shoulder. Ex. 3 at 1-2. At that time, Petitioner exhibited reduced range of motion and expressed an interest in further injections but not surgery or further therapy. *Id*.

⁵ Petitioner's Medicare Part B Summary Notices indicate there are numerous visits to the Michigan Institute of Urology and Oncology & Hematology, PC. Ex. 11. Respondent correctly notes that none of those records have been submitted (Res. Br. at 2, n.1), although their relevance to this claim has not been established.

⁶ Records of the ultrasound examination are referenced (see Ex. 11 at 119) but have not been filed.

III. Affidavits

Petitioner submitted four affidavits in support of his claim, including his own (Ex. 1); an affidavit from his daughter, Joani Stapleton (Ex. 7); an affidavit from his daughter, Shellie Forgione (Ex. 8); and an affidavit from his daughter, Jeani Noelle (Ex. 9).

Petitioner's affidavit states that he received a flu vaccine on January 7, 2019 in his right shoulder. Ex. 1 at 2. He also states that he began to notice "discomfort and pain" in that shoulder as he left the office. *Id.* at 3. "[L]ess than two days later, the pain and discomfort persisted and even worsened." *Id.* The pain persisted over the next several months, and he was told by Dr. Aggarwal that the pain would improve over time. *Id.* at 4. He further stated that "Over the next couple of months, I had very little to no use of my right arm and shoulder." *Id.* at 3. This severe description of his symptoms, however, is inconsistent with the record evidence establishing that he only sought treatment in April 2019 -- four months after his vaccination.

Petitioner's daughter, Shellie Forgione, stated in her affidavit that she lives with her father and recalls that her father received his flu vaccine in January 2019, although she does not specify the precise date. Ex. 8 at 2. Further, Ms. Forgione recalled that her father commented that his vaccine hurt the same day he received it. *Id.* Additionally, she asked her father to play a bowling video game the next day after his vaccination, but he declined because his arm hurt. Ex. 8 at 4. Ms. Forgione's affidavit also states that Petitioner could not use his arm for the remainder of the week and could not lift even small objects like towels or plates. *Id.* at 2. If so, however, it is unclear why Petitioner waited several months more for treatment.

Petitioner also submitted affidavits from his two other daughters providing additional information regarding the onset of his shoulder pain. Joani Stapleton noted that she saw her father at the end of January, who told her at the time that he had shoulder pain from getting a flu shot "a few weeks ago." Ex. 7 at 2. Ms. Stapleton also stated that in early February of 2019 she saw Petitioner "to borrow some moving blankets. [Petitioner] went to pick up 2 blankets and was unable to do so. [Petitioner] explained to me that his arm would not let him pick up the blankets." *Id.* Jeani Noelle stated that the week after Petitioner received his vaccine, he stated his arm was still bothering him. Ex. 9 at 1.

IV. Issue

At issue is whether the onset of Petitioner's pain occurred within 48 hours after vaccination, as set forth in the Vaccine Injury Table and Qualifications and Aids to

Interpretation ("QAI") for a Table SIRVA claim. 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

V. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, 2005 WL 6117475, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569

F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

VI. Finding of Fact

The following fact finding is based on a complete review of the record, including all medical records, affidavits, and additional evidence filed. Specifically, I highlight the following:

- Petitioner received a flu vaccine on January 7, 2019. Ex. 6 at 7.
- On April 8, 2019, Petitioner first noted he was experiencing right shoulder pain, but without specifying the onset. Ex. 6 at 6.
- Petitioner again saw Dr. Aggarwal on July 8, 2019. There is no mention of shoulder pain at that time. Ex. 6 at 3-4. Indeed, Petitioner had a physical examination at this time, which noted that Petitioner "does not appear to be in any acute distress." *Id.* at 3.
- On August 13, 2019, Petitioner reported right shoulder pain that began after a January 2019 flu shot. Ex. 2 at 12.
- On September 3, 2019, Petitioner again complained of shoulder pain that developed after his January flu shot. Ex. 2 at 7.

• Petitioner reported that his shoulder pain began after an injury in January of 2019 when he started physical therapy in October of 2019. Ex. 2 at 12.

Overall, the evidence offered in support of Petitioner's onset allegation is not especially robust, and Respondent has raised reasonable questions about the matter. Nevertheless, I find that the above items of evidence collectively establish (if weakly) that Mr. Klausen's shoulder pain most likely began within 48 hours of receiving the January 7, 2019 flu vaccine. While some of Petitioner's medical records do not reflect a precise date of onset, instead including vague temporal references (i.e., "...in January of 2019 after a flu shot."), he consistently linked the development of his shoulder pain to his vaccination, albeit later in his treatment process. See, e.g., Ex. 2 at 7 (stating his shoulder pain developed after a flu shot in 2019); Ex. 2 at 12 (stating his pain began in January of 2019 after a flu shot).

The delay in seeking treatment is relevant to overall severity (and undercuts claims about the degree of pain he was living with) but does not prevent me from finding onset as alleged. Certainly, there are no intervening records that rebut such a determination. The July 2019 record is not wholly consistent with Petitioner's onset allegations, but it perhaps only underscores that Petitioner's pain was not so acute throughout the relevant time period (another point bearing mostly on damages).

That the onset of Petitioner's injury was within 48 hours of his vaccine is further supported by Petitioner's own declarations, as well as the affidavits of his daughters which describe the onset of Petitioner's condition in greater detail. In particular, Ms. Forgione's affidavit states that she recalled when Petitioner's received his vaccination because they live together. Further, she recalled his pain began immediately following the vaccine. These records are sufficient to establish onset consistent with the Table's requirements. Although this is a close call, petitioners are accorded the benefit of close calls in the Vaccine Program. *Roberts. v. Sec'y of Health & Human Servs.*, No. 09-427V, 2013 WL 5314698, at *10 (Fed. Cl. Spec. Mstr. Aug. 29, 2013).

VII. Conclusion

In view of the evidence of record, I find that there is preponderant evidence that the onset of Petitioner's injury, specifically shoulder pain, was within 48 hours of his vaccine.

VIII. Scheduling Order

Petitioner should proceed with preparing a settlement demand, with supporting documentation, for Respondent's consideration. Petitioner shall also file the records that were identified in Respondent's responsive motion as set forth below. I have reviewed Respondent's argument as to why these records are necessary and agree that Petitioner should file them. As there is no routine discovery in Vaccine cases, it is imperative that Petitioner file all outstanding medical records to avoid undue delay in resolving this case.

Accordingly, the following is ORDERED:

- (1) Petitioner shall file the following medical records by <u>Friday</u>, <u>July 16</u>, 2021:
 - i. Petitioner's Medicare Part B Summary Notices indicate there are numerous visits to the Michigan Institute of Urology and Oncology & Hematology, PC. Ex. 11. Respondent correctly notes that none of those records have been submitted (Res. Br. at 2, n.1). Petitioner shall file these records dating from the three years prior to the vaccination at issue in this case to the present.
 - ii. Records of the ultrasound examination as are referenced in Ex. 11 at 119 from Regional Medical Imaging, P.C.
 - iii. All updated medical records, including any records created after January 16, 2020.
- (2) Respondent shall file, by no later than <u>Friday</u>, <u>July 16</u>, <u>2021</u>, a status report indicating his position in light of this ruling. I strongly encourage the parties to discuss an informal resolution of this case.
- (3) Additional proceedings will be set after the information in this Order is filed.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master